

**ORIGINAL ANTISEPTIC- eucalyptol, menthol, methyl salicylate,
thymol mouthwash
Topco Associates, LLC**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

**Antiseptic Mouthrinse
318.003-318AH-AI**

Active Ingredients

Eucalyptol 0.092%

Menthol 0.042%

Methyl salicylate 0.060%

Thymol 0.064%

Purpose

Antigingivitis, Antiplaque

Use

helps control plaque that leads to gingivitis

Warnings

for this product

Do Not Use

if you have painful or swollen gums, pus from the gum line, loose teeth or increased spacing between the teeth. See your dentist immediately. These may be signs of periodontitis, a serious form of gum disease.

Stop use and ask a dentist if

gingivitis, bleeding, or redness persists for more than 2 weeks

Keep out of reach of children

If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

- do not swallow
- not intended to replace brushing or flossing

adults and children 12 years of age and older vigorously swish 20 mL (2/3 FL OZ or 4 teaspoonfuls) between teeth for 30 seconds then spit out

children under 12 years of age consult a dentist or doctor

Other information

Store at room temperature (59°-77°F).

Inactive ingredients

water, alcohol 26.9%, benzoic acid, poloxamer 407, sodium benzoate, caramel

Disclaimer

*This product is not manufactured or distributed by Johnson & Johnson Healthcare Products, distributor of Original Listerine Antiseptic Mouthwash

TEP

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

Adverse Reactions

DISTRIBUTED BY: TOPCO ASSOCIATES LLC

SKOKIE, IL 60077

QUESTIONS? 1-888-423-0139

topcare@topco.com www.topcobrand.com

Quality Guaranteed

Principal display panel

COMPARE TO LISTERINE*

TopCare

everyday

Antiseptic

Mouthwash

ANTI-GINGIVITIS/ANTIPLAQUE

ORIGINAL FLAVOR

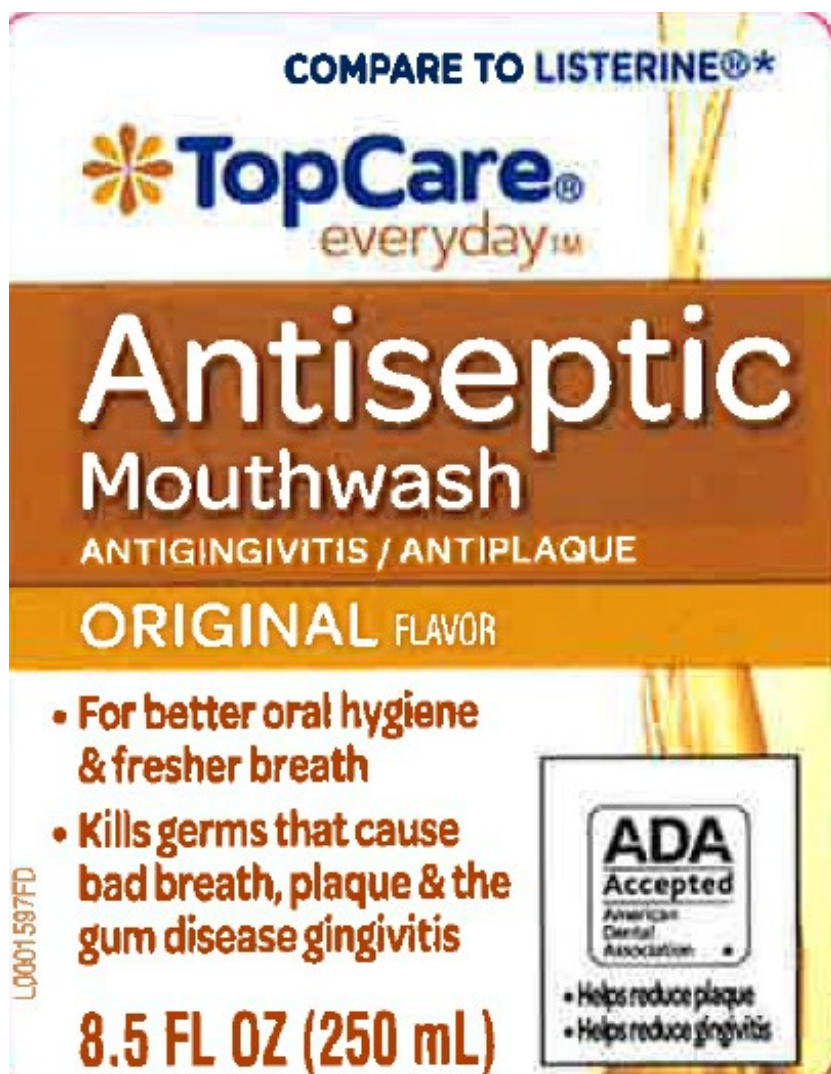
- For better oral hygiene & fresher breath
- Kills germs that cause bad breath, plaque & the gum disease gingivitis

ADA Accepted

American Dental Association

- Helps reduce plaque
- Helps reduce gingivitis

8.5 FL OZ (250 mL)



ORIGINAL ANTISEPTIC

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-318
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
EUCALYPTOL (UNII: RV6J6604TK) (EUCALYPTOL - UNII:RV6J6604TK)	EUCALYPTOL	0.92 mg in 1 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.42 mg in 1 mL
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	0.60 mg in 1 mL
THYMOL (UNII: 3J50XA376E) (THYMOL - UNII:3J50XA376E)	THYMOL	0.64 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CARAMEL (UNII: T9D99G2B1R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-318-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/15/1990	
2	NDC:36800-318-69	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/15/1990	
3	NDC:36800-318-12	1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/15/1990	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	07/15/1990	

Labeler - Topco Associates, LLC (006935977)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(36800-318)

Establishment

Name	Address	ID/FEI	Business Operations
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Vi-Jon, LLC		088520668	manufacture(36800-318)
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Revised: 6/2023

Topco Associates, LLC